

DECLARATION FOR PATENT APPLICATION

As the below-named inventors, we hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am an original, first inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled METHODS OF DETECTING AND TREATING MICROSATELLITE-INSTABILITY POSITIVE TUMORS USING RIZ, the specification of which

			_	is a	attached	hereto a	s Attorney Docket
				No.			
		XX	_	was	filed or	n Decembe	r 17, 2001, as
				App	Lication	Serial N	o. 10/024,450 Attorney
				Doc	ket No.	P-LJ 510	1)
and	was	amended	on	(or	amended	through)	
							(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment(s) referred to above.

I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to myself to be material to patentability as defined in Title 37, Code of Federal Regulations, Sec. 1.56.

Under Sec. 1.56, information is material to patentability when it is not cumulative to information already of

Inventors: Hauang and Serial No.: 10/024,450 Inventors:

Hauang and Chadwick

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record or being made of record in the application, and (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes in: (a) Opposing an argument of unpatentability relied on by the U.S. Patent and Trademark Office, or (b) Asserting an argument of patentability.

I hereby claim the benefit under Title 35, United States Code, § 119(e) of the United States provisional application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application(s) in the manner provided by the first paragraph of Title 35, United States Code § 112, I acknowledge the duty to disclose information that is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 that became available between the filing date of the prior application(s) listed below and the filing date of this non-provisional application:

Application Serial No. Filing Date Status 60/256,582 December 19, 2000 Abandoned

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the

Inventors: Hauang and Chadwick Serial No.: 10/024,450

Filed:

December 17, 2001

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United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of first inventor: Shi Huang							
Inventor's signature:							
Date: 5-29-02							
Residence: San Diego, California USA							
Citizenship: China							
Mailing Address: 5296 Timber Branch Way San Diego, California 92103							
Full name of second inventor: Robert B. Chadwick							
Inventor's signature:							
Date:							
Residence: Castro Valley, California USA							
Citizenship: United States of America							
Mailing Address: 5719 Shadow Ridge Drive							

Castro Valley, California 94552

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Înventors:

Hauang and Chadwick

Serial No.:

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Page 3

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Date:							
Residence: San Diego, California USA							
Citizenship: China							
Mailing Address: 5296 Timber Branch Way San Diego, California 92103							
Full name of second inventor: Robert B. Chadwick Inventor's signature:							
Date:							
Residence: Castro Valley, California USA							
Citizenship: United States of America							
Mailing Address: 5719 Shadow Ridge Drive							

Castro Valley, California 94552

#4

SEP 1 3 2002 E

PATENT

Our Docket: P-LJ 5101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Huang and Chadwick
)

Serial No. 10/024,450
)

Filed: December 17, 2001
)

For: METHODS OF DETECTING AND)

TREATING MICROSATELLITE-)
INSTABILITY POSITIVE
)
TUMORS USING RIZ
)

Commissioner for Patents
Washington, D.C. 20231

Sir:

SMALL ENTITY STATEMENT

The U.S. Patent and Trademark (USPTO) permits parties that establish status as a Small Entity to pay certain reduced fees (all citations to 37 C.F.R. § 1.27 except as noted). To be entitled to Small Entity Status, a party must be at least one of the following:

(1) Individual person:

An individual person, including an inventor and persons to whom an inventor has transferred some rights in the invention. § 1.27(a)(1).

(2) Small business concern:

A business concern whose number of employees, including affiliates, does not exceed 500 persons. § 1.27(a)(2) (incorporating 13 C.F.R. § 121.802).

"Business concern" means individual proprietorship, partnership, limited liability company, corporation,

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joint venture, association, trust or cooperative. If the concern is a joint venture, participation by foreign business entities may not be more than 49%. 13 C.F.R. § 121.105.

The "number of employees" is the average number of employees, including the employees of its domestic and foreign affiliates, based on numbers of employees for each of the pay periods for the preceding completed 12 calendar months. "Employees" includes all individuals employed on a full-time, part-time, temporary, or other basis. Part-time and temporary employees are counted the same as full-time employees. If a concern has not been in business for 12 months, use the average number of employees for each of the pay periods it has been in business. 13 C.F.R. § 121.106.

Concerns are "affiliates" of each other when one concern directly or indirectly controls or has the power to control the other, or when a third party or parties controls or has the power to control both concerns. 13 C.F.R. § 121.103(a).

(3) Nonprofit organization:

A university or other institution of higher education located in any country. § 1.27(a)(3) (ii)(A).

An organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a). Also included are such organizations located in a foreign country that would qualify if it were located in this country. § 1.27(a)(3)(ii)(B),(D).

A nonprofit scientific or educational organization qualified under a nonprofit organization statute of a U.S. state. Also included are such organizations located in a foreign country that would qualify if it were located in this country. § 1.27(a)(3)(ii)(C),(D).

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Please note that a license to the Government resulting from a rights determination under Executive Order 10096 does not constitute a license that would prohibit claiming Small Entity Status. Similarly, for small business concerns and nonprofit organizations, a license to a Federal agency resulting from a funding agreement with that agency under 35 U.S.C. § 202(c)(4) is not a license that would prohibit claiming Small Entity Status. § 1.27(a)(4).

I hereby assert that I am empowered to sign on behalf of the party identified below ("Party"). Persons empowered to sign include, but are not limited to, an inventor him- or herself or an authorized officer of an assignee or licensee.

See § 1.27(c)(2).

I have made a determination of the Party's entitlement to Small Entity Status, including a determination that all parties holding rights in the invention qualify for Small Entity Status. § 1.27(f).

I hereby assert that the Party has not assigned, granted, conveyed or licensed--and is under no obligation under contract or law to do so--any rights in the invention to any other party that would not qualify as a Small Entity. If the rights in the invention held by the Party are not exclusive, the other parties having rights in the invention are **The Ohio State** University and Dcantix, Inc. Separate assertions of Small Entity Status should be obtained from each party having rights to the invention.

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I hereby assert that the Party is entitled to be accorded Small Entity Status by the USPTO for the application or patent identified above. § 1.27(c)(1).

I understand that Small Entity Status must be newly determined when the issue fee and each maintenance fee is due. If there is any change resulting in loss of entitlement to Small Entity Status, I acknowledge the duty to file a notification to the USPTO in this application or patent before or upon paying the fee. § 1.27(g).

I understand that Small Entity Status must be separately established in any related application, including continuation, divisional, continuation-in-part, continued prosecution application or reissue application. § 1.27(c)(4).

I understand that any attempt to establish Small Entity Status improperly, deceptively or fraudulently will be considered a fraud practiced on the USPTO and may result in abandonment of the application or jeopardize the validity and enforceability of any resulting patent. § 1.27(h).

Chipust 16, 20

Date

Name: John Campbell

Title: Director of Intellectual Property

THE BURNHAM INSTITUTE
10901 North Torrey Pines Road
La Jolla, California 92037



Y

POWER OF ATTORNEY FOR PATENT APPLICATION BY ASSIGNEE

Assignee The Burnham Institute is a co-owner of the entire right, title and interest of U.S. patent application Ser. No. 10/024,450, filed on December 17, 2001, as attorney docket number P-LJ 5101, and entitled METHODS OF DETECTING AND TREATING MICROSATELLITE-INSTABILITY POSITIVE TUMORS USING RIZ, and any subsequently filed divisional, continuation, continuation-in-part or reissue application, including international and foreign applications claiming priority thereto.

The Assignee hereby appoints the following attorneys to prosecute these applications and to transact all related business in the United States Patent and Trademark Office and any international and foreign patent offices:

CATHRYN CAMPBELL, Registration No. 31,815; DAVID A. GAY, Registration No. 39,200; CALVIN A. FAN, Registration No. 38,444; ANDREA L. GASHLER, Registration No. 41,029; JAMES J. WONG, Registration No. 34,949; DEBORAH L. CADENA, Registration No. 44,048; MELANIE K. WEBSTER, Registration No. 45,201; ASTRID R. SPAIN, Registration No. 47,956; and KIMBERLY J. PRIOR, Registration No. 41,483.

Please direct all telephone calls to Cathryn Campbell at (858) 535-9001 and address all correspondence to:

CATHRYN CAMPBELL
CAMPBELL & FLORES LLP
4370 La Jolla Village Drive
7th Floor
San Diego, California 92122
USPTO CUSTOMER NO. 23601

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 $$\operatorname{\mathtt{The}}$ undersigned is authorized to sign on behalf of the Assignee.

Signature:

Name (typed):

John Campbell

Title:

Director of Intellectual Property

Assignee:

THE BURNHAM INSTITUTE

Date:

21 2002



ONE EXECUTED STATEMENT UNDER 37 C.F.R. § 3.73 (b) WITH ATTACHED COPIES OF TWO ASSIGNMENTS (7 pages) Attorney Docket No: P-LJ 5101

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

"EXPRESS MAIL" MAILING LABEL NUMBER: EV 065 744 855 US

DATE OF DEPOSIT: September 13, 2002

I HEREBY CERTIFY THAT THIS PAPER OR FEE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE "EXPRESS MAIL POST OFFICE TO ADDRESSEE" SERVICE UNDER 37 CFR 1.10 ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO COMMISSIONER FOR PATENTS, WASHINGTON, D.C. 20231.

Printed Name of Person Mailing Paper or Fee

Signature of Person Mailing Paper or Fee



STATEMENT UNDER 37 C.F.R. § 3.73(b)

Title of Application:

METHODS OF DETECTING AND TREATING

MICROSATELLITE-INSTABILITY POSITIVE

TUMORS USING RIZ

Application Ser. No.:

10/024,450

Filed:

December 17, 2001

Inventor(s):

Huang and Chadwick

Attorney Docket No.:

P-LJ 5101

THE BURNHAM INSTITUTE, a non-profit organization, states that it is a co-assignee with The Ohio State University of the entire right, title and interest in the patent application identified above by virtue of an assignment from an inventor of the application. A copy of the executed assignment, submitted for recording, is attached hereto as documentary evidence of the chain of title to the assignee.

The undersigned is empowered to sign this statement on behalf of the assignee.

Date: //ay 21, 2002

Signature:

Name: John Campbell

Title: Director of Intellectual Property



ASSIGNMENT

This Assignment is made by Shi Huang of San Diego, California, Assignor, to The Burnham Institute, Assignee, having a place of business at 10901 North Torrey Pines Road, La Jolla, California 92037.

WHEREAS, Assignor is a joint inventor of a new and useful METHODS OF DETECTING AND TREATING MICROSATELLITE-INSTABILITY POSITIVE TUMORS USING RIZ for which an application for United States Letters Patent was filed on December 17, 2001, in the United States Patent and Trademark Office, bearing Serial No. 10/024,450, and identified as Attorney Docket No. P-LJ 5101.

WHEREAS, Assignor believes that Assignor is one of the original joint inventors of the invention disclosed and claimed in said application for Letters Patent; and

WHEREAS, the parties desire to have a recordable instrument assigning the entirety of Assignor's right, title and interest in and to said invention, said application and any Letters Patent that may be granted for said invention in the United States and throughout the world;

NOW, THEREFORE, in accordance with the obligations to assign the invention and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Assignor sells, assigns, and transfers to Assignee, the entirety of Assignor's right, title, and interest in and to said invention, said application, any applications entitled to benefit of priority to said application under Title 35, United States Code, Sections 120, 121 or 251, which include divisionals, continuations and reissues, and any Letters Patent that may be granted on said invention or these applications and any Letters Patent that may be granted that may be granted for said invention in the United States and throughout the world, including the right to file foreign applications directly in the name of the Assignee and to claim for any such foreign applications any priority rights to which such applications are entitled under international conventions, treaties, or otherwise.

Assignor agrees that, upon request and without further compensation, but at no expense to Assignor, Assignor and Assignor's legal representatives and assigns will do all lawful acts, including the execution of papers and the giving of testimony, that may be necessary or desirable for obtaining, sustaining, reissuing, or enforcing Letters Patent in the United States and throughout the world for said invention, and for

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perfecting, recording, or maintaining the title of Assignee, its successors and assigns, to said invention, said application, and any Letters Patent granted for said invention in the United States and throughout the world.

Assignor represents and warrants that Assignor has not granted and will not grant to others any rights inconsistent with the rights granted herein.

Assignor authorizes and requests the Commissioner of Patents and Trademarks and all foreign countries to issue any Letters Patent granted for said invention, whether on said application or on any subsequently filed divisional, continuation, or reissue application, to Assignee, its successors and assigns, as an assignee of the entirety of Assignor's interest in said invention.

Serial No.:

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Filed:

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IN WITNESS WHEREOF, Assignor has executed this Assignment on the date(s) provided below.

Aşsignor: Shi Huang

5-29-02

Date

STATE OF COUNTY OF

29th 2007 before mes personally appeared The buch

 \overline{X} personally known to me - OR - $\overline{\ }$ Oproved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/spe/they, executed the same in his/her/their authorized capacity(i/s), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(\$\square\$) acted, executed the instrument.

WITNESS by hand and official seal.

(Signature of Notary)





ASSIGNMENT

This Assignment is made by Robert Chadwick of Bothell, Washington, Assignor, to The Ohio State University, Assignee, having a place of business at 1960 Kenny Road, Columbus, Ohio, 43210.

WHEREAS, Assignor is a joint inventor of a new and useful METHODS OF DETECTING AND TREATING MICROSATELLITE-INSTABILITY POSITIVE TUMORS USING RIZ for which an application for United States Letters Patent was filed on December 17, 2001, in the United States Patent and Trademark Office, bearing Serial No. 10/024,450, and identified as Attorney Docket No. P-LJ 5101.

WHEREAS, Assignor believes that Assignor is one of the original joint inventors of the invention disclosed and claimed in said application for Letters Patent; and

WHEREAS, the parties desire to have a recordable instrument assigning the entirety of Assignor's right, title and interest in and to said invention, said application and any Letters Patent that may be granted for said invention in the United States and throughout the world;

NOW, THEREFORE, in accordance with the obligations to assign the invention and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Assignor sells, assigns, and transfers to Assignee, the entirety of Assignor's right, title, and interest in and to said invention, said application, any applications entitled to benefit of priority to said application under Title 35, United States Code, Sections 120, 121 or 251, which include divisionals, continuations and reissues, and any Letters Patent that may be granted on said invention or these applications and any Letters Patent that may be granted that may be granted for said invention in the United States and throughout the world, including the right to file foreign applications directly in the name of the Assignee and to claim for any such foreign applications any priority rights to which such applications are entitled under international conventions, treaties, or otherwise.

Assignor agrees that, upon request and without further compensation, but at no expense to Assignor, Assignor and Assignor's legal representatives and assigns will do all lawful acts, including the execution of papers and the giving of testimony, that may be necessary or desirable for obtaining, sustaining, reissuing, or enforcing Letters Patent in the United States and throughout the world for said invention, and for

Serial No.: 10/024,450

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Attny Docket: P-LJ 5101

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perfecting, recording, or maintaining the title of Assignee, its successors and assigns, to said invention, said application, and any Letters Patent granted for said invention in the United States and throughout the world.

Assignor represents and warrants that Assignor has not granted and will not grant to others any rights inconsistent with the rights granted herein.

Assignor authorizes and requests the Commissioner of Patents and Trademarks and all foreign countries to issue any Letters Patent granted for said invention, whether on said application or on any subsequently filed divisional, continuation, or reissue application, to Assignee, its successors and assigns, as an assignee of the entirety of Assignor's interest in said invention.

Serial No.:

10/024,450

Filed:

December 17, 2001

Attny Docket: P-LJ 5101

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IN WITNESS WHEREOF, Assignor has executed this Assignment on the date(s) provided below.

Assignor: Robert B. Chadwick

Signature

Date

STATE OF COUNTY OF

personally appeared'

personally known to me - OR - proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) (3)/are subscribed to the within instrument and acknowledged to me that he she/they executed the same in his/her/their authorized capacity(ies), and that by his her their signature(s) on the instrument the person(), or the entity upon behalf of which the person (x) acted, executed the instrument.

WITNESS by hand and official seal.

CORA JUDD COMM. # 1300861 OTARY PUBLIC - CALIFORNIA ALAMEDA COUNTY My Comm. Expires APR 14, 2005 7